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The California Birth Def	Tects Monitoring Progr	am (CBDMP) compl	eted its	study on the	
"Feasibility of Investig	ating Whether There i	s a Relationship	Between	Birth Defects and	
Service in the Gulf War"	under contract #DAMI	) 17-96-1-6044 wi	th the De	epartment of Defense	
(DOD). CBDMP completed	all the research aims	specified in th	e origina	al proposal. The	
CBDMP found that:					
1. DOD data about birth	defects to active du	ity military pers	onnel is	sufficient to allow	
	a collection staff to	dentity medica	i records	during the rist	
year of life.	ew to identify conger	uital anomalies i	s feasib	e for DOD hospitals.	
2. Hospital record review to identify congenital anomalies is feasible for DOD hospitals.  3. The computerized discharge index from military hospitals is extremely incomplete and					
	to complete hospital				
4. The demographic info	rmation on California	based Reserve a	nd Nation	nal Guard personnel	
was not sufficient to allow linkage to vital statistics birth files and, by extension,					
CBDMP data.					
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# Feasibility of Investigating Whether There is a Relationship Between Birth Defects and Services in the Gulf War

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#### Introduction:

There was much concern about the possible effects on reproductive outcomes from a wide variety of exposures to military personnel deployed to the Persian Gulf beginning August 1990. These exposures included 1) heat, 2) infectious agents, 3) botulin toxoid and anthrax vaccine, 4) smoke from oil fumes, 5) depleted uranium munitions, 6) pesticides, and 7) stress. The one study to address the risk for all birth defects was based only on data from the military computerized hospitalization discharge summary and showed no effect of any Gulf War exposure<sup>1</sup>. Because of the controversy surrounding this study, the Veterans Administration and Department of Defense (DOD) contracted with the California Birth Defects Monitoring Program (CBDMP) to evaluate the completeness and accuracy of the military hospital discharge summary and to determine the feasibility of more completely studying birth defects risk among military personnel. Specifically, the aims of CBDMP's study were to determine:

- If DOD data, the computerized hospitalization discharge summary about births to active duty military personnel, is sufficient to allow CBDMP hospital data collection staff to identify medical records during the first year of life.
- 2) Whether hospital record review to identify congenital anomalies, the standard that CBDMP uses for the civilian population in California, is feasible for DOD facilities, which may be closed all together, or for which there may not be up-to-date medical record information.
- 3) If DOD computerized hospitalization discharge summary information about structural congenital anomalies among active duty military personnel is accurate and complete compared to complete hospital medical record review.
- 4) If DOD information about the identity of inactive duty military personnel can be linked to the California Vital Statistics birth files and CBDMP data.

### **Body:**

- Specific Aim #1: To determine if the DOD data about births to active duty personnel is sufficient to allow the CBDMP to locate medical records during the first year of life about those children.
- Specific Aim #2: To determine whether hospital record review to identify congenital
  anomalies, the standard that CBDMP uses for the population in California, is feasible for
  DOD facilities which may be closed altogether, or for which there may not be up-to-date
  medical record information.

### Methods:

The infants included in this study were children born between May 1, 1991 and May 31, 1994 to Gulf War veterans and non-deployed veterans who were active duty personnel in the Army, Navy, Marine Corps or Air Force, posted or stationed in California. The DOD Manpower Data Center in Monterey Bay, California provided discharge summary data for all hospitalization records in military hospitals in California between January 1991 and September 1994 with International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes in any of the 8 diagnosis fields indicating: live births (V30-V39 and V27.0-V27.9, respectively), abortions, multiple gestation codes, relative difference in size of fetal head and pelvis, known or suspected fetal abnormality affecting management of mother. Though we were interested only in live births occurring between May 1, 1991 and May 31, 1994, we requested information from DOD for the broader time period January 1, 1991 until September 30, 1994 to assure that all infants born during May 1991 until May 1994 were part of our files. Military records contained Gulf War service information so deployment status could be assessed. The Gulf War service data included dates of activation, number of days of activation, in-theatre participation dates and number of days in-theater, service and component of participation. We received these data in

nine files and standardized the format of these files so they could be appended into one data set. We omitted duplicate admission records from analysis. We considered a DOD record to be a duplicate if it matched on: SSN, source of admission, birth date, beneficiary category, admission date, discharge date, disposition status, Dimensional Measuring Interface Standard (DMIS) ID of reporting facility, family member prefix, military treatment facility (MTF) service, sex, and zip code. We linked records for babies admitted to the same facility more than once, as well for those seen at more than one MTF, and each unique diagnosis code was appended to the baby's file. The total number of children born in California MTFs, according to the DOD files was compared to the total number of children born in these facilities according to California Vital Statistics (VS) (Appendix A). In order to evaluate the completeness of the data we used the births for the same time period, January 1, 1991 through September 30, 1994, in the VS file to compare with the DOD file. The DOD files contained one to eight ICD-9 diagnostic codes for each of these children. We sorted the data set using the congenital malformation codes routinely used by the CBDMP to find potential cases of children with birth defects (Appendix B). The DOD admissions were inclusive through the baby's first birthday, similar to CBDMP procedures for case ascertainment in civilian hospitals. Medical records from military hospitals are "retired" to the National Personnel Records Center (NPRC) in St. Louis, 3-5 years after the last admission date or in the event that the facility should close. The NPRC requires sponsors' and babies' names, sponsor's SSN, admission date, baby's birth date, and MTF in order to pull medical records. The original data files did not have sponsors' and babies' names. The CBDMP sent files containing baby's date of birth, baby's sex, and sponsor's SSN for each case (a baby with a birth defect) and control to the DOD. The DOD matched the files to the Defense Eligibility Enrollment Reporting System (DEERS) database where the names were located. The DOD was

unable to match 81 cases to babies names because they were not registered into the system's database. However, each of these 81 cases was matched to a sponsor's name. To find additional baby names, CBDMP staff matched the 81 cases to the VS live birth data for years 1991-1994 by facility and baby's birth date. We used the baby's first name and last name in the VS file if the VS father's surname or the VS mother's maiden name matched the DOD sponsor's name, and the VS baby birth date and the VS hospital code matched the DOD data. We merged the babies' and sponsors' names into the MTF hospitalization files using the baby's birth date, baby's sex, and SSN.

The Department of the Army, the Department of the Navy, and the Department of the Air Force wrote letters granting CBDMP access to military medical hospitals. However, it took years to obtain authorization from the Surgeon General's Human Subjects Research Review Board (HSRRB). By this time, the authorization from each branch of the military had expired. We therefore, re-sent authorization packets to all branches of the military requesting approval to review medical records. We received approval from the Departments of the Army, Air Force, and Navy to review medical records in 1999. We also received approval to conduct this research from the California Committee for the Protection of Human Subjects in 1996, which was successfully renewed each year.

#### **Results:**

The DOD file in general identified over 97% of the hospital births identified by California VS files. The CBDMP found that DOD computerized hospitalization discharge summary data about births to active duty military personnel is sufficient to allow CBDMP's data collection staff to identify medical records during the first year of life. The CBDMP found that hospital record review to identify congenital anomalies is feasible for DOD hospitals. CBDMP was able

to adequately review hospital records to identify children with congenital anomalies. In fact, our impression was that military hospital records are as up-to-date and complete as the records in all but the best of civilian hospitals. Despite the fact that some military hospitals had been closed, we retrieved 94% of charts among cases, 97% of charts among controls either in the military facility itself or in St. Louis at the NPRC. A total of 447 babies born between January 1, 1991 and September 30, 1994 found in the DOD computerized hospitalization discharge summary data set had at least one of the 39 birth defects CBDMP selected for study (with complete sponsor and baby name). A total of 149 (33%) had a sponsor deployed to the Gulf War.

 Specific Aim #3: To determine if the DOD computerized hospitalization discharge summary information about structural congenital anomalies among offspring of active duty military personnel is accurate and complete compared to hospital medical record review.

### Methods:

To identify children with congenital anomalies identified during the first year of life, CBDMP staff visits 176 hospitals and genetic centers serving one half of the state of California to review information from <u>multiple</u> sources. These sources include pediatric subspecialty and obstetric admission logs, pathology records, genetic center clinical and laboratory logs, birth, and death certificates, and the computerized hospitalization discharge summary.

After reviewing information from these sources, CBDMP asks hospitals to provide medical records for any "sick" child. CBDMP staff review approximately five times as many charts, as that which is eventually abstracted. This system of "active surveillance" is performed by a trained staff of data collection specialists to identify children with birth defects, and is considered to be the gold standard nationwide. Because the purpose of this study was to evaluate the DOD computerized hospitalization discharge summary, we used only that source to identify children with birth defects at military hospitals. CBDMP used similar procedures for abstracting medical records at DOD facilities as we use in civilian hospitals in California.

Out of all the children with major and minor congenital anomalies, we have reported on 39 birth defects. These congenital anomalies were selected because they are severe, and clinical diagnostic criterion for inclusion of cases is clear. The Center for Disease Control request data on a similar set of conditions. For this study, CBDMP designed and implemented an on-line data collection system used for abstracting clinical data (Appendix C) and its data collection

procedure manual (Appendix D). We also modified an on-line system, which we used for diagnostic coding and on-line review of all clinical data. Because of the delays in receiving authorization from the HSRRB, most of the medical records were retired to the NPRC for storage. We requested all medical charts of infants with the congenital malformation codes routinely used by CBDMP, regardless of the sponsors Gulf War deployment status. We compared the total number of cases found in the DOD computerized hospitalization discharge summary to what we actually confirmed by chart review. We requested to review a total of 447 case records (children identified with a birth defect on the computerized hospitalization discharge summary) and a random sample of 450 control records (children identified as healthy on the computerized hospitalization discharge summary). We retrieved a total of 422 case records at the NPRC and San Diego Naval Medical Center resulting in a 94% ascertainment rate. Of these 422 records found, 140 (33.2%) had sponsors that were in-theater during the Gulf War. Of the 450 control records that we requested, we received 436, resulting in a 97% ascertainment rate. Supervisors and data collection specialists reviewed medical records at the NPRC in July 1999 and May 2000. CBDMP data collection specialist staff also reviewed records at the San Diego Naval Medical Center in November 1999 and June 2000. Upon review of these medical records, we found that there were 10 babies known to be transferred to civilian hospitals and 13 transferred to other MTFs for additional care. However, these 13 subsequent admissions to other MTFs did not appear on the DOD computerized hospitalization discharge summary. In order to clarify the diagnostic information on these cases, data collection staff reviewed and abstracted the 10 records at the civilian hospitals and the 13 records at other MTFs.

For all abstracted congenital anomaly cases, we used the same quality control procedures that we employ for CBDMP's registry data among civilian hospitals to verify and validate

diagnostic information. A data collection supervisor reviewed all completed abstracts for accuracy and consistency. A supervisor re-abstracted a random sample of the completed abstracts. Then, her abstract was compared to the data collection specialist's abstract, and any discrepancies were reconciled. Each abstract was coded using British Pediatric Association codes routinely used at CBDMP from 1991-1994 in order to accurately compare the rate of birth defects found on the MTF cases to the rates in our Registry for the same period of time. We used a slightly modified version of the on-line coding system that is used routinely at CBDMP. The system consists of blind double entry followed by a "compare and reconcile" process. This process compares the codes assigned by each coder and any discrepancies are then reconciled. Once the coding process was completed, the abstracts were merged to form the baby's case, i.e. if the baby was seen at more than one facility, an abstract was completed at each facility where the baby had reportable diagnoses. A panel of CBDMP staff reviewed each case. This panel included a physician, research associate, coder, and the project manager. The cases were reviewed in order to evaluate the quality, consistency, and accuracy of the data.

We matched multiple records for hospital admission for each baby on the computerized hospitalization discharge summary DOD abstracted data set by baby's first name and last name, birth date, birth hour, sex, plurality and SSN. One unique case identification number was assigned to each baby. We matched the abstract from military hospital charts to the DOD computerized hospitalization discharge summary file using the matching variables: SSN, sponsor name, and birth date.

Out of 447 case records, three children had sponsors who were grandfathers; we excluded these children from the study. For 22 other children we could not locate the charts for our review. Our a priori hypothesis, based on work with the civilian hospitals, was that the

computerized hospitalization discharge summary was both incomplete and inaccurate compared to complete hospital medical review. So as not to bias the study in the direction of our hypothesis, for analyses we generously assumed that the charts of all of these 22 children contained the same information as the computerized hospitalization discharge summary. (This assumption lowers the missed case percentages in Table 2, column 1.) The data set was subsetted to include only the period of interest: births occurring between May 1,1991 - May 31, 1994. This time period was used for analyzing birth defect outcomes since Gulf War veterans would have given birth to offspring nine months or more after to being exposed to potential teratogens after their initial deployment in August 1990. The final analytic data set contained 369 babies with both major and minor congenital anomalies, out of which, we report on 39 conditions in Tables 1 and 2.

In Table 2, the method for calculation of confidence intervals follows the 95% confidence intervals for the percent difference between the expected number of birth defects (Table 1, Column A) based on the CBDMP rates and the observed number (Table 1, Column C) is calculated from an expression given by Breslow and Day (Statistical Methods in Cancer Research, Oxford University Press, 1987). In symbols, the confidence bounds are calculated for the ratio 100\*(A - C)/A. These bounds are based on an approximation and require that the expected number of cases not be subject to random variation. The fact that more than 32,000 cases are used to estimate the expected values means that the accuracy of the confidence interval bounds is only very slightly affected. That is, the source of random variation is overwhelmingly determined by the variation in the observed number of birth defects. As usual, these 95% confidence intervals provide a range of likely values for the true underlying ratios.

The 95% confidence interval for the ratio of the observed number of defects not confirmed by chart review (Table 1, Column D) to the number observed from the discharge summary (Table 1, Column C) results from application of standard statistical techniques. The variance of the logarithm of the ratio D/B is estimated by variance (log(ratio)) = 1/B + 1/D. The confidence interval follows by applying a normal approximation using this variance and converting the interval to bounds for the 'true' ratio estimated by D/B. The process is analogous to constructing a confidence interval for an odds ratio or a rate ratio and is explained in detail in a number of introductory biostatistics texts.

Table 1: Comparison of Observed # of Birth Defects on DOD Discharge Summary Compared to Medical Record Review  May 1991-May 1994					
Birth Defect:		A Expected # of birth defects (CBDMP rates)	B Observed # of birth defects in discharge summary	C Observed # in discharge summary confirmed by chart review	D Observed # in discharge summary not confirmed by chart review
Central Nervous System	îşî deye. Yê				
Anencephaly		5	3	3	0
Spina Bifida w/ &w/o hydrocepha	aly	11	8	8	. 0
Hydrocephaly w/o spina bifida		15	13	5	8
Encephalocele		3	3	1	2
Microcephalus	į	33	17	15	2
Eye Anophthalmia/Micropthalmia		9	i	0	1
Congenital Cataract		5	6	4	2
Aniridea/Iris anomalies	į	4	0	0	0
Anotia/Microtia		8	3	3	0
Cardiovascular System Common Truncus		2	0	0	0
Trans. of Great Arteries		14	4	4	0 .
Tetralogy of Fallot		10	11	6	5
Endocardial Cushion		11	6	5	1
Aortic Valve Stenoses		6	2	0	2
Hypoplastic Left Heart Syndrome	:	5	5	4	1
Coarctation of the Aorta		11	5	4	1
Pulmonary Valve Atresia	İ	8	0	0	0
Tricuspid Valve Atresia		3	2	2	0
Ebstein's Anomaly		2	1	0	1
Orofacial	a symmetriae chemicaga a en Carrollo del Pelone				a sensan and a sensan and a
Cleft Palate w/o cleft lip		16	29	25	4
Cleft Lip with and w/o cleft palate	•	33	29	28	1
Choanal Atresia	İ	5	6	1	5
Gastrointestinal Esophagal Atresia/TEF Rectal Atresia		7 13	4 11	4 8	0 3
Hirschprung's		5	8	3	5
Biliary Atresia		3	1	1	0
Genitourinary Renal Agenesis		6	9		1
Bladder Exstrophy		1	0	0	0
Obstructive g-u defect		46	61	38	23
Musculóskeletal					
RD- upper		11	12	10	2
RD- lower		5	5	2	3
Gastroschisis	ļ	7	29	11	18
Omphalocele		5	53	3	50
Diaphragmatic Hemia		8	6	2	4
<b>Chromosomal</b> Trisomy 13		3	0	0	0
Downs Syndrome		40	28	19	9
Trisomy 18		4	4	4	0
Other Fetal Alcohol Syndrome		4	3	1	2
Amniotic Bands		5	8	5	3

Table 2: Birth Defect Errors on Discharge Summary					
May 1991- May 1994					
Birth Defect	% Missed cases on discharge summary	95% Confidence Intervals	% False positive cases on discharge summary	95% Confidence Intervals	
Central Nervous System					
Anencephaly	40.0	-19.4 to 60.2	0.0	N/A	
Spina Bifida w/&w/o hydrocephaly	27.3	-8.9 to 45.6	0.0	N/A	
Hydrocephaly w/o spina bifida	66.7	-43.9 to 76.4	61.5	25.5 to 148.5	
Encephalocele	66.7	-12.7 to 80.7	66.7	11.1 to 399.0	
	54.5	39.5 to 63.7	11.8	2.7 to 50.9	
Microcephalus					
An anhthologic Africanthologic	100.0	N/A	100.0	6.3 to 1598.8	
Anophthalmia/Micropthalmia	20.0	-44.2 to 45.0	33.3	6.7 to 165.2	
Congenital Cataract		-44.2 to 45.0 N/A	N/A	N/A	
Aniridea/Iris anomalies	100.0			1	
Anotia/Microtia	62.5	25.4 to 75.1	0.0	N/A	
Cardiovascular System					
Common Truncus	100.0	N/A	N/A	N/A	
Trans. of Great Arteries	71.4	48.5 to 80.3	0.0	N/A	
Tetralogy of Fallot	40.0	3.8 to 56.6	45.5	15.8 to 130.8	
Endocardial Cushion	54.5	23.4 to 67.8	16.7	2.0 to 138.4	
Aortic Valve Stenoses	100.0	N/A	100.0	14.1 to 709.9	
Hypoplastic Left Heart Syndrome	20.0	-44.2 to 45.0	20.0	2.3 to 171.2	
Coarctation of the Aorta	63.6	34.5 to 75.0	20.0	2.3 to 171.2	
Pulmonary Valve Atresia	100.0	N/A	N/A	N/A	
Tricuspid Valve Atresia	33.3	-56.7 to 58.0	0.0	N/A	
Ebstein's Anomaly	100.0	N/A	100.0	6.3 to 1598.8	
Orofacial					
Cleft Palate w/o cleft lip	0	-94.2 to -30.5	13.8	4.8 to 39.2	
Cleft Lip with and w/o cleft palate	15.2	-4.1 to 28.5	3.4	0.5 to 25.3	
Choanal Atresia	80.0	32.4 to 88.4	83.3	25.4 to 273.1	
Gastrointestinal					
Esophagal Atresia/TEF	42.9	-3.0 to 60.7	0.0	N/A	
Rectal Atresia	38.5	7.9 to 54.0	27.3	7.6 to 97.8	
Hirschprung's	40.0	-19.4 to 60.2	62.5	20.4 to 191.1	
Biliary Atresia	66.7	-12.7 to 80.7	0.0	N/A	
Genitourinary					
Renal Agenesis	0	-99.6 to 0.2	11.1	1.4 to 87.7	
Bladder Exstrophy	100.0	N/A	N/A	N/A	
Obstructive g-u defect	17.4	1.7 to 28.8	37.7	23.3 to 60.9	
Musculoskeletal					
RD- upper	9.1	-29.9 to 30.3	16.7	3.7 to 74.5	
RD- lower	60.0	6.0 to 74.8	60.0	14.3 to 251.1	
Gastroschisis	0	-120.6 to -21.7	62.1	34.5 to 111.8	
Omphalocele	40.0	-19.4 to 60.2	94.3	64.1 to 138.8	
Diaphragmatic Hernia	75.0	41.2 to 84.3	66.7	18.8 to 236.2	
Chromosomal					
Trisomy 13	100.0	N/A	N/A	N/A	
Downs Syndrome	52.5	38.9 to 61.2	32.1	15.2 to 68.1	
Trisomy 18	0.0	-80.2 to 31.2	0.0	N/A	
Other		00.2 to 51.2			
Fetal Alcohol Syndrome	75.0	15.5 to 85.5	66.7	11.1 to 399.0	
Amniotic Bands	0.0	-68.4 to 29.2	37.5	9.9 to 141.4	
Annioue Danus	1 0.0	-00.7 10 29.2	31.3	7.7 10 171.7	

#### **Results:**

Table 1 compares the observed number of birth defects on the DOD computerized hospitalization discharge summary (column B) compared to the expected number of birth defects (column A). The expected number of birth defects is calculated by multiplying 32,046, the number of military hospitals' births between May 1, 1991 and May 31, 1994 in California by the rate of birth defects the CBDMP found in civilian hospitals during the same time period. Again, for the purpose of this study, we consider the CBDMP congenital anomaly rates to be the "gold standard." In Table 1, data in column C are the number of cases identified on the computerized hospitalization discharge summary that are confirmed by chart review. The data in column D reflect the number of cases identified on the DOD computerized hospitalization discharge summary that are not confirmed by chart review and is calculated by subtracting the number in column C from the number in column B.

Table 2 shows summary information pertinent to the accuracy and completeness of the DOD computerized hospitalization discharge summary. The first column is the percentage of actual cases of congenital anomalies estimated to be missed on the DOD computerized hospitalization discharge summary. It is calculated for each type of congenital anomaly by using data in Table 1:

(A - C)/column A x 100%.

If C is greater than A, the % of missed cases on the computerized hospitalization discharge summary is reported as 0%.

The next column in Table 2 is the false positive cases on the DOD computerized hospitalization discharge summary index. False positives are cases identified on the

computerized hospitalization discharge summary that are <u>not</u> confirmed by medical record review. It is calculated for each type of congenital anomaly by using data from Table 1:

Column D/column B x 100%.

If the numbers in column B and column D from Table 1 are both zero, the value is reported in Table 2 as not applicable (N/A).

In Table 2, the wide confidence intervals result from the low number of observed cases, however, we used all the available data about children with birth defects. Table 2 shows that the DOD computerized hospitalization discharge summary is very incomplete. The missed case percentage estimates for most types of congenital anomalies are very high. Furthermore, what is recorded on the computerized hospitalization discharge summary is inaccurate, since the percent false positive case on the computerized hospitalization discharge summary is also very high for most types of congenital anomalies. Furthermore, even when the computerized hospitalization discharge summary identifies children with congenital anomalies, it is incomplete in identifying all of the diagnoses. In this data set, there were 42 other congenital anomaly diagnoses identified through chart review that were not identified on the computerized hospitalization discharge summary. Among the 436 healthy controls, for which there was no congenital anomaly diagnoses on the computerized hospitalization discharge summary, no children had a severe congenital anomaly in one of the 39 categories upon review of the medical record.

### **Discussion and Conclusion:**

The data shows that the DOD computerized hospitalization discharge summary is very inaccurate and incomplete in California. This result is very similar to the result found by Hexter, Harris, and Roeper, et al. regarding the computerized discharge summary index for civilian hospitals in California.

Why is this the case? Regarding missing cases, when CBDMP staff reviewed medical records, we found that there were 42 additional confirmed diagnoses of one of the conditions listed in Tables 1 and 2 compared to 237 conditions (the total for column C) that were both observed on the computerized hospitalization discharge summary and confirmed by medical chart review.

We did not find any birth defects in the 39 categories among a random sample of 436 controls. While the control sample is small, this finding suggests that another possible reason for missed cases is the lack of ascertainment of children of military personnel at civilian hospitals. In this study, we knew of ten children who were transferred to civilian hospitals from military hospitals. However, the actual numbers of children diagnosed and treated in civilian hospitals is likely to be much higher. CBDMP's experience is that only about one half of all the severe congenital anomalies shown in Tables 1 and 2 are readily apparent at birth. This means that the many children born in military hospitals will be discharged home as healthy, only to be seen on outpatient later, and then referred to pediatric sub-specialists at civilian hospitals for diagnostic work up, and medical and surgical interventions. Because of this kind of referral pattern, a priori, we would predict that the DOD computerized hospitalization discharge summary alone would miss many children with structural anomalies diagnosed at civilian hospitals. The data in the first column of Table 2 is consistent with this a priori hypothesis.

It is possible that there is a "healthy worker" effect among military personnel, and rates of birth defects among military personnel are actually lower than rates of birth defects that CBDMP finds among civilians. However, this theory can only be proved with complete ascertainment of birth defects among military personnel at civilian hospitals, which was beyond the scope of this study.

Why are there false positives on the DOD computerized hospitalization discharge summary? First, we found that certain ICD 9 codes encompass both major and minor anomalies. For example, the four-digit ICD 9 code for gastroschisis (a severe congenital anomaly) is also the same four-digit code for diastases recti, a much more common, but clinically insignificant problem. Similarly, the ICD 9 codes are the same for choanal atresia, a life threatening congenital anomaly, and choanal stenosis, again a much more common, clinically unimportant problem.

In addition to the problem of combining major and minor anomalies in the ICD 9 codes, we found that many children in DOD facilities get a diagnoses such as "rule out" transposition of the great vessels in the medical record. This diagnosis is coded as transposition of the great vessel on the computerized hospitalization discharge summary, even though that diagnosis has been ruled out. This "over coding" is particularly common when hospital reimbursement is tied to the severity of the diagnoses being considered. These problems with over diagnoses on the DOD computerized hospitalization discharge summary are the same problems that CBDMP found in the civilian hospital discharge summary.

Given the degree of misclassification shown in Table 2, the CBDMP recommends that the VA and the DOD establish a complete population-based registry of congenital anomalies for children of military personnel using active surveillance of civilian as well as military hospitals. With such data, and only with data, can reproductive risks from future exposures be properly evaluated.

The CBDMP found 25 children in DOD medical records with cleft palate without cleft lip, while 16 would be expected (Table 1), and 11 cases of gastroschisis, while only 7 could be expected. The reason for these excesses is unclear, but further study is warranted.

The misclassification shown in Table 2, with missed diagnoses and false positive cases makes the DOD computerized hospitalization discharge summary index a poor source for assessing the health impact of exposure among military personnel deployed to the Persian Gulf. Unfortunately, the prior work on congenital anomaly rates among Gulf War deployed and non-deployed military personnel was based on the computerized hospitalization discharge summary and was reported as showing no effect from exposures experienced by Gulf War veterans. Our data in this monograph suggest that the results of this prior study should be viewed with extreme caution.

• Specific Aim #4: To determine if DOD demographic information of Reserve and National Guard personnel residing in California (CA Reservists) at the time of activation is sufficient to allow linkage to VS birth files and the CBDMP Birth Defects Registry data to locate children born to CA Reservists.

#### Methods:

To address this aim we conducted a linkage study to VS files. This linkage is important if birth defect rates are to be calculated. CBDMP staff attempted to link the 5,304 reservists who were deployed in-theatre to the California VS birth data (January 1991-December 1994) (n=610,701). CBDMP links its data to VS files using the following variables: baby date of birth; baby surname; baby first name; baby birth hour; baby birth weight; mother maiden name; mother first name; mother residence county and zip code; father surname; and father first name. The DOD did not have information as to whether the reservist had a baby at all, let alone the name and birth date of children. The VS data does not contain SSN, which is present on DOD files. Therefore, we attempted to link the two data sets using only demographic variables. We used the father's birth date on the VS files to try to match to the sponsor's last name, sponsor's first name, and sponsor's birth date on the DOD record.

#### **Results:**

A match was counted only if variables were the same, only 61 matches were found - a match rate of 1.2%. Using any combination of two variables: sponsor first name, last name, or birth date resulted in 2,049 matches, a match rate of 39%. For some unknown number of cases, a match is not possible because many CA Reservists had no children born to them. The results of linking the DOD demographic information of CA Reservists to CBDMP data would be similar to those reported here because CBDMP data are linked to VS data.

In summary, the CBDMP found that the demographic information for CA Reservists was not sufficient to allow linkage to VS birth files, and by extension, CBDMP data. Thus, we had insufficient information to assess the number of births among CA Reservist, let alone the rate of congenital anomalies in that population.

### **Key Research Accomplishments:**

- CBDMP found that the DOD computerized hospitalization discharge summary data about births to active duty military personnel is sufficient to allow CBDMP's hospital data collection staff to identify medical records during the first year of life.
- CBDMP found that hospital record review to identify congenital anomalies is feasible for
   DOD hospitals.
- CBDMP found that the computerized hospitalization discharge summary from military
  hospitals is extremely <u>incomplete</u> and <u>inaccurate</u> compared to complete hospital medical
  record review.
- CBDMP found that the demographic information on CA Reservists was not sufficient to allow linkage to VS birth files, and by extension, CBDMP data.

### **Reportable Outcomes:**

In June 2000 we presented an abstract entitled "Evaluation of the Department of Defense Database as a Source for Birth Defect Surveillance" (Appendix E) and poster at the 2000 California Maternal and Child Health Conference.

### **Conclusions:**

The CBDMP completed its study on "The Feasibility of Investigating Whether There is a Relationship Between Birth Defects and Service in the Gulf War" under contract # DAMD17-96-1-6044 with the DOD. CBDMP completed all the research aims specified in the original proposal. The CBDMP found that:

- 1) The DOD computerized hospitalization discharge summary (about births) to active duty military personnel <u>is sufficient</u> to allow CBDMP's hospital data collection staff to identify medical records during the first year of life
- 2) Hospital record review to identify congenital anomalies is feasible for DOD hospitals.
- 3) The computerized hospitalization discharge summary from military hospitals <u>is extremely</u> incomplete and inaccurate compared to complete hospital medical record review
- 4) The demographic information on CA Reservists <u>was not sufficient to allow linkage</u> to VS birth files and, by extension, to CBDMP surveillance data.

The CBDMP recommends that the VA and the DOD establish a complete population-based registry of congenital anomalies for children of military personnel using active surveillance of civilian as well as military hospitals. With such data, and only with such data, can reproductive risks from future exposures be properly evaluated.

### Addendum:

After we receive comments on this report, we anticipate preparing a manuscript for publication. We will share this manuscript with you for peer review according to the stipulations of the contract.

### Personnel:

- K. Broker, Budgets and Accounting Manager
- C. Clark, Data Collection Manager
- K. Deosaransingh, Research Associate
- M. Doleman, Data Steward/Coder
- S. Edde, Data Collection Specialist
- J. Harris, M.D., M.P.H., Principal Investigator
- S. Kammeraad, Data Collection Specialist
- L. Mann, Data Collection Specialist
- J. Novielli, Data Collection Specialist
- G. Shaw, Dr.Ph., Distinguished Scientist, Epidemiologist
- P. Smith, Programming Supervisor
- C. Stickney, Data Collection Specialist Supervisor
- B. Warmerdam, Project Manager
- J. Wynne, Community Liaison
- S. Young-Tem, Word Processing

### References:

- 1. Cowan DN, DeFraites RF, Gray GC, et al. The risk of birth defects among children of Persian Gulf War Veterans. N Engl J Med 1997; 336:1650-6.
- 2. Hexter AC, Harris JA, Roeper P, et al. Evaluation of the hospital discharge diagnoses index and the birth certificate as sources of information on birth defects. Public Health Rep 1990; 105:296-307.

# Bibliography:

Deosaransingh K, Harris JA, Warmerdam BA. Evaluation of the department of defense database as a source of birth defect surveillance. 2000 California Maternal and Child Health Conference, San Diego CA, June 2000.

# Appendices

	Total Live Births in Military Hospitals (1991-19	991-1994) Compared to Total Live Births on Vital Statistics	to Total L	ive Births	on Vital St	atistics			
18O	HOSP(MIIITAR) HOSPITAL	DOD-1991 VS-1991 DOD-1992 VS-1992 DOD-1993 VS-1993 WDOD 1994	/S-T991 T	OD-1992	VS-1992	<b>50</b> 6-1993	VS-1993	DOD 1994	VS-1994*
50,	502 San Diego/Naval Med Center-Balboa	3547	3660	3198	3237	3274	3397	2420	2454
1	17 Alameda/NH Oakland	1126	1145	1066	1081	873	907	588	009
99	664 Yuba/USAF Hosp Marysville (Beale AFB)	276	279	247	248	94	94	85	85
35	350 Merced/Castle AFB	325	329	0	0	0	0	0	0
10.	103 Kern/Edwards AFB	321	320	331	331	289	289	218	221
47.	475 San Bernardino/George AFB	137	179	0	0	0	0	0	0
43	431 Riverside/March AFB	724	725	683	684	424	483	125	125
44.	444 Sacramento/Mather AFB	498	499	437	439	411	411	138	138
29.	597 Solano/David Grant Mc Travis	1088	1093	1188	1191	962	1050	707	734
26,	564 Santa Barbara/Vadenberg AFB	145	248	261	264	227	229	163	176
36.	363 Monterey/Hays AH FT Ord	1452	1485	1105	1107	415	416	0	0
69	693 San Bernardino/Weed AH FT Irwin	289	288	333	341	393	398	156	284
46	461 San Bernardino/NH 29 Palms	437	441	646	651	552	568	459	464
11,	112 Kings/NH Lemoore	387	397	423	433	347	353	244	250
20.	501 San Diego/ NHCamp Pendelton	1084	1102	089	683	1085	1086	768	875
12	122 Lassen/US Army Hosp	0	-	0	0	0	0	0	0
	Total	11836	12191	10598	10690	9346	,9681	6071	6406
	Difference(VS-DOD)	355		92		335		335	
	% Difference (VS minus DOD)/VSx100	2.90%		%06.0		3.50%		2%	
	**Only Jan-Sept for 1994								

# CALIFORNIA BIRTH DEFECTS MONITORING PROGRAM REPORTABLE ICD-9-CM CODES FOR ABSTRACTING FORM 01

The following list is to be used for abstracting reportable conditions.

Diagnostic Index	
052.0 -052.9	Congenital varicella (chickenpox)
054.3	Herpes Encephalitis
090.0-090.9	Congenital Syphilis
228.1	Cystic hygroma
243.0	Congenital hypothyroidism
259.4	Dwarfism, NOS
279.11	DiGeorge Syndrome, hypoplasia of thymus
331.3-331.4 348.0	Hydrocephalus - communicating or obstructive Arachnoid cyst
352.6	Mobius syndrome
520.0-520.9	Disorders in tooth development, and eruption (excluding 520.3, 520.6, 520.7)
524.0-524.9	Dentofacial anomalies
551.1, 552.1, 553.1	Omphalocele
560.0	Intussusception
658.80-658.83	Amniotic bands
740.0-759.9	Congenital anomalies
760.71	Fetal alcohol syndrome
771.0-771.2	Congenital rubella, CMV, toxoplasmosis, herpes
778.0	Nonimmune hydrops fetalis
770.0	Office ( ) to the second of th

Note: Wilm tumor, facial palsy, myotonic dystrophy, fetal teratoma are all NR for abstracting, but have associated congenital anomalies that are reportable. Document the above diagnoses in the nonreportable box on the abstract. See BPA for exceptions to the above.

Stillbirth (only in combination with above anomalies)

779.9

# REPORTABLE CHROMOSOMAL CONDITIONS

REPORTABILITY

1. The normal chromosome complement:

46,XX (female) 46,XY (male)

Never

**Always** 

2. An increase or decrease in the total

number of chromosomes from the normal 46:

69,XXX

45,X OR 45, XO

92,XXYY

47,XX,mar+

48,XXXX

47,XY,+21

48,XXYY 47,XXY

47,XXX

47,XX,f+

Common Words:

Down Syndrome

Edward Syndrome

Klinefelter Syndrome

Patau Syndrome

Tetraploidy

Triploidy

Trisomy

Turner Syndrome

Combination

3. Exception to above (2): Robertsonian

translocations (or centric fusions)

which are normal variants. These have

a decreased chromosome number of 45;

but a normal amount of genetic material:

45,XX,t(13q14q)

45,XY,rob(13;14)(p11;q11)

45,XX,-13,-14+t(13q14q)

4. The presence of a marker chromosome:

47,XXX,mar+

47,XY,mar+

47,XX,f+

5. Deletions of chromosomal material:

46,XX,del(5)(p13)

46,XY,del(13)(q21q33)

46,XX,5p- (Cri-Du-Chat Syndrome)

46,XY,4p- (Wolf Syndrome)

6. The presence of a ring chromosome:

46,XY,r(6)(p24q26)

Ring 18

Always

Always

Always

Attachment D2-b:Rev 10/92

15. Mosaics containing any of these above numbers (3, 8, 10, 11) with each other (but not with a reportable condition):

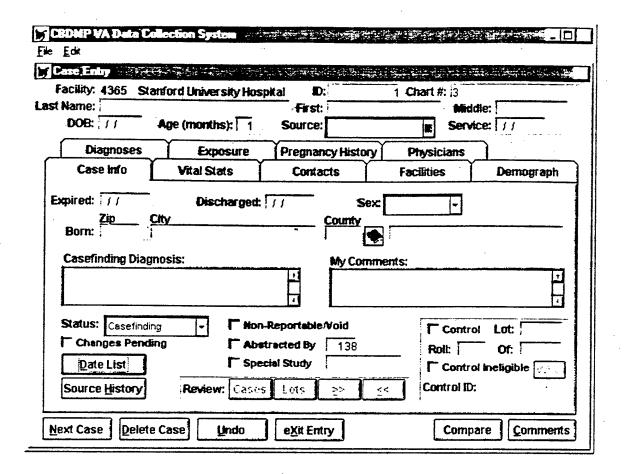
46,XX/45,XX,rob(13;14) 46,XY/46XX,21s+

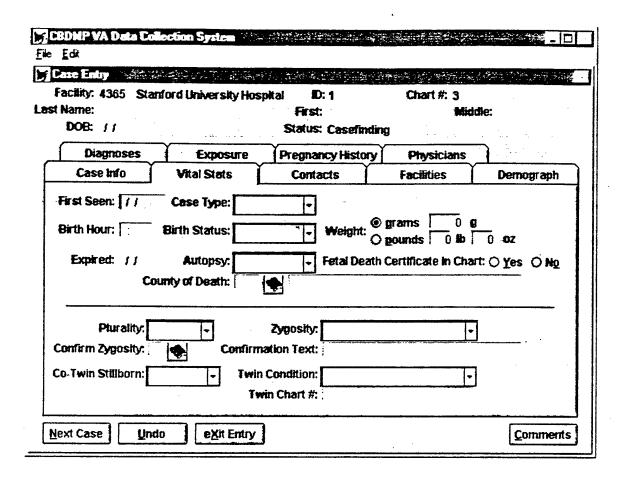
46,XX/46XX,9qh+

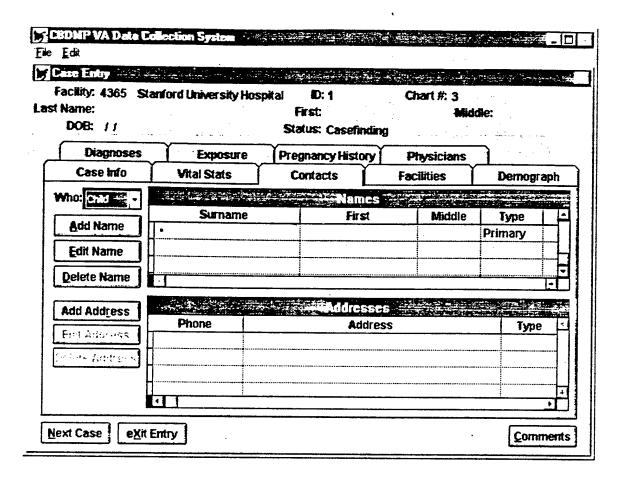
16. Mosaics (two or more chromosomally different cell lines) containing any of these above numbers (2, 4, 5, 6, 7, 9, 12):

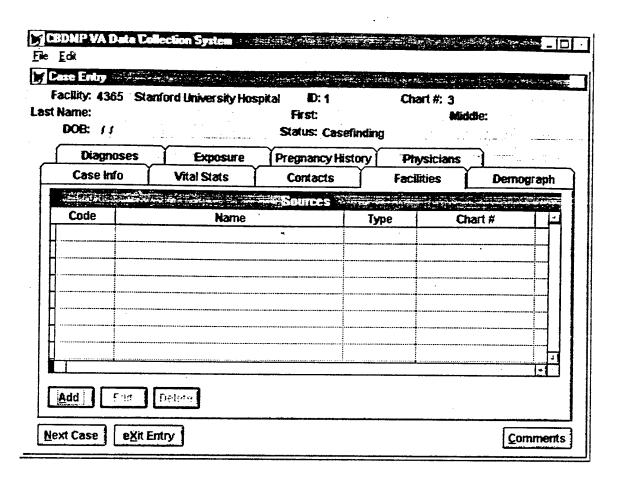
45,X/46,XX 46,XX/46,XX,del(5)p13 46,XX/47,XX,+21 45,X/46,XX,t(2;5)(q21,q31) 46,XY/47,XY+8mos Never

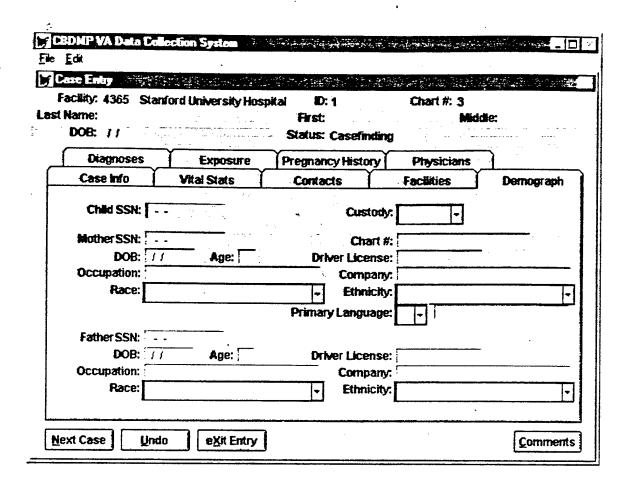
Always

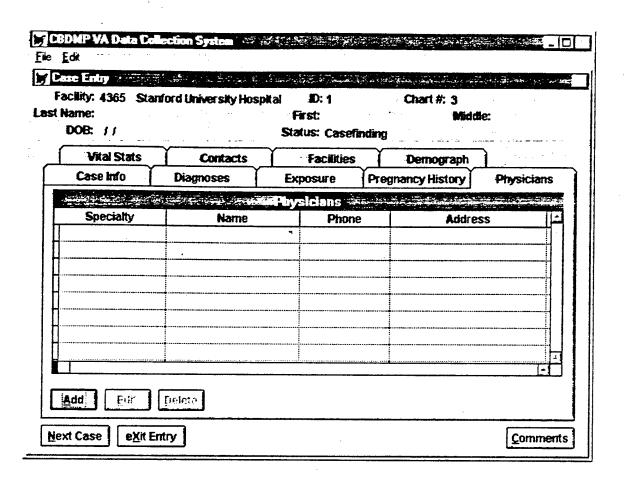


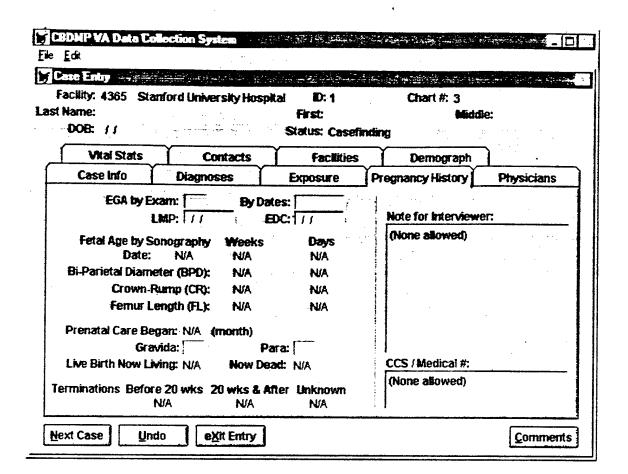


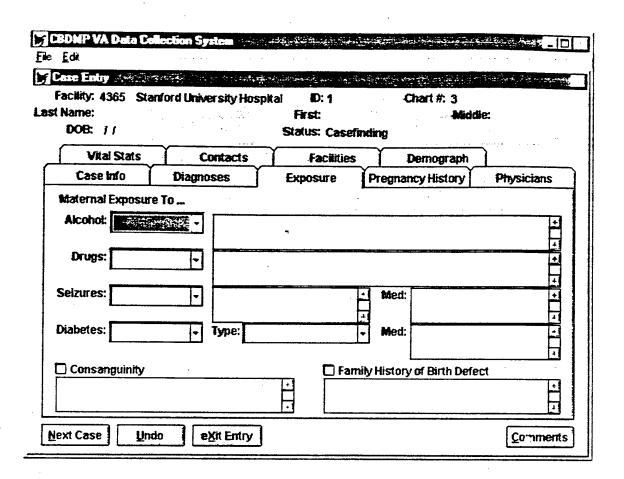


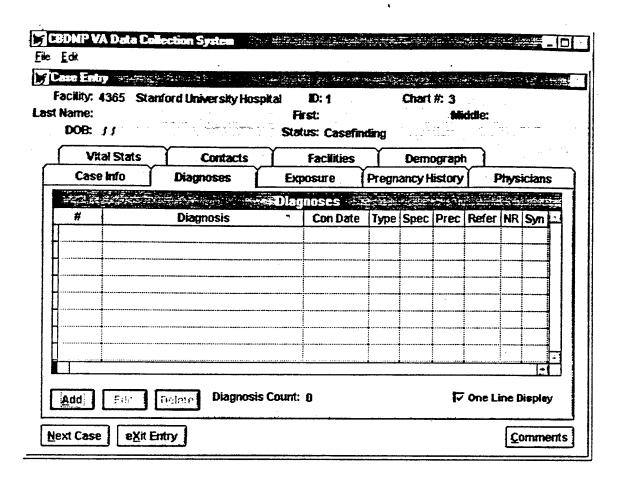














Feasibility Of Investigating
Whether There Is A
Relationship Between
Birth Defects and Service
in the Gulf War

# FEASIBILITY OF INVESTIGATING WHETHER THERE IS A RELATIONSHIP BETWEEN BIRTH DEFECTS AND SERVICE IN THE GULF WAR

The following instructions are for the study named above and commonly referred to as the "VA Study." They apply to the modified On-line abstracting system of the CBDMP and will be utilized when abstracting records at the National Personnel Records Center (NPRC) in St. Louis, MO.

All current screens (tabs) on the VA-DCS system are the same as the regular On-line system with a few minor alterations.

The military treatment facilities (MTFs) that we will encounter are:

#### Air Force Facilities:

### Facility Code:

Beale AFB (9th Med Group Hospital, Marysville)	5815
Castle AFB (93 <sup>rd</sup> Strategic, Merced)	2410
David Grant Medical Center (Travis AFB)	4825
Edwards AFB (95th Med Group Hospital, Kern Co.)	1560
George AFB (83 <sup>rd</sup> Med Group, San Bernadino)	3695
March AFB (722 <sup>nd</sup> Med Group, Riverside)	3358
Mather AFB (323 <sup>rd</sup> Med Group, Sacramento)	3445
Vandenberg AFB (30 <sup>th</sup> Med Group, Santa Barbara Co.)	4240

# Army Facilities:

 Note: Watch for abbreviations: AMC – Army Medical Center AH – Army Hospital

Hays Army Hospital	(Fort Ord) -	<del></del> 2715
Weed Army Hospital	(Fort Irwin)	)3616

# Navy and Marine Facilities:

Note: Watch for abbreviations: NMC – Naval Medical Center
 NH – Naval Hospital

Camp Pendelton Naval Hospital (Oceanside)	3761
Lemoore Naval Hospital (Kings Co.)	
Oakland Naval Medical Center (Alameda Co.)	0155
San Diego Naval Medical Center (Balboa)	3762
29 Palms Naval Hospital (MCAGCC,San Bernardino)	3631

# ABSTRACTING "CASES"

Cases are those children that were reported by the Dept. of Defense (DoD) to have a birth defect. Create an abstract for each of these children even if they prove to have no birth defect as defined by the CBDMP. (See Diagnoses Screen for further details.)

# Case Entry and Case Info Screen:

Abstract what we currently collect, with the exception of having to supply a Source. We do not have to fill in that box.

The Chart # will be the Veteran's (sponsor's) SS # and should be entered with the appropriate dashes. PROOF THIS NUMBER!

#### Vital Stats Screen:

Collect the same information that we collect for routine CBDMP cases.

#### Contacts Screen:

We will collect information on the Child, MOB and FOB <u>only.</u> No other contacts are necessary.

#### Facilities Screen:

Record all facilities, both military and civilian. The military facilities codes are listed on Page 1 of these instructions. Use the CBDMP facility codes for all civilian hospitals.

A birth facility must be recorded for each case. If unknown, record as such.

## Demographics Screen:

Collect all information, paying special attention to Social Security Numbers. N/A those boxes for which you do not have information.

# Physicians Screen:

Record no physicians.

# Pregnancy History Screen:

Record: EGA by exam and dates

LMP and EDC Gravida/Para

It is not necessary to fill out any of the remaining boxes.

# Exposure Screen:

Follow the current CBDMP guidelines. N/A those that don't apply or for which you have no information.

## Diagnoses Screen:

Use the BPA inclusion list that the CBDMP was using during the 1991-94 period. These will be provided for you.

If a child that was noted by the DOD statistics to have a birth defect, does <u>not</u> have one by our guidelines, an abstract <u>must be created</u>, stating that the defect was ruled out/never stated/or whatever the case may be. Document very carefully in the <u>DIAGNOSIS</u> Box the sequence of events. What is <u>not</u> documented in the chart is important! See the following examples.

- 1) If a child was diagnosed with a defect that is clearly ruled out by specific tests or by a specialist, use a <u>Ruled out</u> diagnosis.
- Example: TOF ruled out 040593 5 9 2
   Echocardiogram showed normal heart. Echo evidently placed on chart after discharge of child. No other postnatal tests done. Mention is made of a prenatal U/S that could have indicated a heart problem.
- 2) If a child was diagnosed with a defect that is not mentioned or never substantiated by any test, procedure or physician, use a <u>"No evidence of"</u> diagnosis.
- Example: No evidence of omphalocele 040593 2 6 2 Pediatrician examined child and gave a diagnosis of umbilical hernia. "Protrusion of the umbilicus. No evidence of abdominal wall defect."
- 3) If a child was diagnosed with isolated ASD, VSD, PDA, or pulmonic stenosis—conditions that may be well documented on the chart, but are not reportable under CBDMP criteria, use an "Isolated " diagnosis."
- Example: Isolated VSD 040593 5 9 2
   Echocardiogram revealed small muscular VSD. No mention of treatment or meds. Child discharged home with no follow-up.
- Note: All diagnoses in above examples have precisions of 2. The diagnosis can be coded but will not count as an anomaly.

Do not use the Comments Box for any documentation regarding a diagnosis. The actual test/procedure will go in the Test/Procedures box for diagnoses with a confirmation greater than clinical. The comments about the diagnosis itself will go in the Diagnoses Box. (This is to expedite analysis.)

We will include all inpatient diagnoses—even those from transferring facilities. Be sure to document, however, exactly where the diagnosis came from.

Example: Tricuspid atresia 5 9 12
 Echocardiogram in chart from referring Children's Hospital, San Diego revealed atresia and child is to undergo BT shunt.
 Note: (Remember, of course, to put the referred/referring hospital in the Facilities tab.)

Specific Diagnoses:

Microcephaly – Record head circumference. Include in Diagnosis box. Note if not available.

**Hydrocephaly** -- Distinguish from ventriculomegaly by looking for precise tests and diagnoses made by specialists. Record head circumference. Note if not available.

Valvular stenosis vs. atresia – Distinguish between the two by looking for precise tests and diagnoses made by specialists.

Rectal atresia vs. Large intestine atresia — Distinguish between the two by looking for precise tests and diagnoses made by specialists.

Transposition of Great Vessels – Give accurate and detailed description of the anomaly.

Omphalocele and Gastroschisis – Distinguish between the two by looking for precise diagnoses made by specialists.

#### ABSTRACTING CONTROLS

Do not complete an abstract for a normal baby. Mark off of the master log.

If the child has an anomaly reportable under the CBDMP criteria, create an abstract using the above instructions.

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# • EVALUATION OF THE DEPARTMENT OF DEFENSE DATABASE AS A SOURCE FOR BIRTH DEFECTS SURVEILLANCE

Kamala Deosaransingh MPH, Barbara A. Warmerdam, John A. Harris MD MPH California Birth Defects Monitoring Program, California Department of Health Services

**Background:** Several studies have used the Department of Defense (DOD) hospitalization data as a source to examine the risk of birth defects among the children of Gulf War veterans. The DOD hospitalization data are collected in a manner similar to the hospital discharge diagnosis index, which has been found to be incomplete in reporting birth defects. This study evaluates the completeness of the DOD hospitalization database as a source of birth defect information among the children of Gulf War veterans.

Methods: Military hospitalization data were obtained for infants born in military hospitals in California between 1991 and 1994. The expected number for 38 selected birth defects categories was calculated using California baseline rates from the California Birth Defects Monitoring Program (CBDMP) registry. The CBDMP conducts population-based, active case ascertainment of birth defects, therefore these registry data were considered the gold standard. Chi-square analyses were conducted to determine statistically significant differences between the observed and expected numbers.

Results: The CBDMP registry included 1,164,357 live births with 20,849 birth defects. The DOD dataset included 38,279 live births with 490 birth defects. In five (13%) of the 38 birth defects categories examined, the observed number of cases was less than expected. In six (16%) of the birth defects categories the observed number was greater than expected. Conclusions: Similar to the hospital discharge diagnostic index, the DOD hospitalization data appear to be limited in reporting the prevalence of selected birth defects.

Implications: Abstraction of the entire military medical record is needed to determine the

**Implications:** Abstraction of the entire military medical record is needed to determine the reasons for possible underreporting or misclassification of birth defects in the DOD hospitalization database.

This work was supported by the Department of the Army, Grant #DAMD 17-96-1- to the Calfornia Birth Defects Monitoring Program.